Introduced by Senator Speier

February 20, 2003

An act to amend Section 4052 of, and to add Section 4427 to, the Business and Professions Code, relating to pharmacists.

LEGISLATIVE COUNSEL'S DIGEST

SB 545, as introduced, Speier. Emergency contraception drug therapy.

Existing Law, the Pharmacy Law, provides for the licensing and regulation of the practice of pharmacy under the jurisdiction of the California State Board of Pharmacy. Existing law requires a pharmacist to provide consultation when furnishing drugs, with certain exceptions, and the board has set forth specific requirements applicable to the provision of consultation and the maintenance of patient medication records. Existing law authorizes a pharmacist, in addition to other functions, to initiate emergency contraception drug therapy if the pharmacist has completed a training program on emergency contraception and certain other conditions are met.

This bill would remove this training requirement. The bill would also state that the provisions authorizing the initiation of emergency contraception drug therapy do not impose a duty on a pharmacist to provide consultation different from or to maintain patient medication records that differ from that which is generally required by the board's regulations. The bill would, however, require a pharmacist to ask questions necessary to determine a patient's eligibility for the therapy. The bill would also prohibit a pharmacist from charging a separate consultation fee for the initiation of emergency contraception drug therapy.

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Existing law provides for the Medi-Cal program, administered by the State Department of Health Services, under which qualified low-income persons are provided with health care services, including prescription benefits. Under existing law, the department pays participating pharmacists a discounted price for drugs on the Medi-Cal drug formulary.

This bill would require a pharmacy that participates in the Medi-Cal program to offer the initiation of emergency contraception drug therapy. The bill would prohibit a pharmacist initiating emergency contraception drug therapy from charging a dispensing fee in excess of the dispensing fee charged to Medi-Cal patients.

Existing law makes it a misdemeanor to knowingly violate the Pharmacy Law. All other violations of that law are infractions unless otherwise indicated.

Because this bill would create new prohibitions on pharmacists, the violation of which would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

- SECTION 1. It is the intent of the Legislature to ensure equality of access to pharmaceuticals for the women of California.
- In ensuring that access, the Legislature intends to eliminate
- discriminatory practices relating to emergency contraception,
- which treat women differently from other classes of patients who
- receive their prescriptions through pharmacies.
- SEC. 2. Section 4052 of the Business and Professions Code 7 8 is amended to read:
- 4052. (a) Notwithstanding any other provision of law, a 9 10 pharmacist may:
- (1) Furnish a reasonable quantity of compounded medication 11 to a prescriber for office use by the prescriber.

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(2) Transmit a valid prescription to another pharmacist.

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- (3) Administer, orally or topically, drugs and biologicals pursuant to a prescriber's order.
- (4) Perform the following procedures or functions in a licensed health care facility in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:
- (A) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.
 - (B) Ordering drug therapy-related laboratory tests.
- (C) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).
- (D) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.
- (5) (A) Perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance, as applicable, with policies, procedures, or protocols of that facility, the home health agency, the licensed clinic, the health care service plan, or that physician, in accordance with subparagraph (C):
- (i) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.
 - (ii) Ordering drug therapy-related laboratory tests.
- (iii) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).
- (iv) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the

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patient's prescriber for the individual patient, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this clause within 24 hours.

- (B) A patient's prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.
- (C) The policies, procedures, or protocols referred to in this paragraph shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and, at a minimum, meet all of the following requirements:
- (i) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.
- (ii) Require that the medical records of the patient be available to both the patient's prescriber and the pharmacist.
- (iii) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.
- (iv) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.
- (6) Manufacture, measure, fit to the patient, or sell and repair dangerous devices or furnish instructions to the patient or the patient's representative concerning the use of those devices.

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(7) Provide consultation to patients and professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals.

(8) Initiate emergency contraception drug therapy in accordance with standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice. Prior to performing any procedure authorized under this paragraph, a pharmacist shall have completed a training program on emergency contraception, which includes, but is not limited to, conduct of sensitive communications, quality assurance, referral to additional services, and documentation. A pharmacist may not charge a separate consultation fee to a patient for emergency contraception drug therapy that is initiated pursuant to this section, and may not charge a dispensing fee that is in excess of the dispensing fee charged to Medi-Cal patients for the initiation of emergency contraception drug therapy pursuant to this section.

This paragraph does not impose a duty on a pharmacist to do any of the following:

- (A) Provide a consultation different from that required pursuant to Section 1707.2 of Title 16 of the California Code of Regulations, except that a pharmacist shall ask questions necessary to determine patient eligibility for the initiation of emergency contraception drug therapy.
- (B) Maintain patient medication records that differ from the requirements specified in Section 1707.1 of Title 16 of the California Code of Regulations.
- (b) (1) Prior to performing any procedure authorized by paragraph (4) of subdivision (a), a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.
- (2) Prior to performing any procedure authorized by paragraph (5) of subdivision (a), a pharmacist shall have either (A) successfully completed clinical residency training or (B) demonstrated clinical experience in direct patient care delivery.
- (3) For each emergency contraception drug therapy initiated pursuant to paragraph (8) of subdivision (a), the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized factsheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using

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the drug, the need for medical followup, and other appropriate

- information. The board shall develop this form in consultation
- with the State Department of Health Services, the American
- College of Obstetricians and Gynecologists, the California
- 5 Pharmacists Association, and other health care organizations. The
- provisions of this section do not preclude the use of existing publications developed by nationally recognized medical
- organizations. 9

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- (c) Nothing in this section shall affect the requirements of existing law relating to maintaining the confidentiality of medical 10
- 12 (d) Nothing in this section shall affect the requirements of existing law relating to the licensing of a health care facility. 13
 - SEC. 3. Section 4427 is added to the Business and Professions Code, to read:
 - 4427. As a condition for the participation of a pharmacy in the Medi-Cal program pursuant to Chapter 7 (commencing with Section 14000) of Division 9 of the Welfare and Institutions Code, the pharmacy shall offer as a service the initiation of emergency contraception drug therapy.
- 20 SEC. 4. No reimbursement is required by this act pursuant to 22 Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California
- 29 Constitution.